

**§405.2124 Calculation of utilization rates for comparison with minimal utilization rate(s) and notification of status.**

For purposes of classification the Secretary will use either the utilization rate for the preceding 12 months or the average utilization rate of the preceding 2 calendar years, whichever is higher. The Secretary will inform each ESRD facility and the network coordinating council of the network area in which the ESRD facility is located of the results of this classification.

**§405.2130 Condition: Minimum utilization rates.**

Unless a renal transplantation center is granted an exception under §405.2122(b), the center must meet the following minimum utilization rate(s) for unconditional or conditional status:

(a) Unconditional status: 15 or more transplants performed annually.

(b) Conditional status: 7 to 14 transplants performed annually.

[55 FR 23441, June 8, 1990]

**§405.2131 Condition: Provider status: Renal transplantation center or renal dialysis center.**

A renal transplantation center or a renal dialysis center (§405.2102(e) (1) or (2)) operated by a hospital may qualify for approval and be reimbursed under the ESRD program only if the hospital is otherwise an approved provider in the Medicare program.

**§405.2132 [Reserved]**

**§405.2133 Condition: Furnishing data and information for ESRD program administration.**

The ESRD facility, laboratory performing histocompatibility testing, and organ procurement organization furnishes data and information in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs, for inclusion in a national ESRD medical information system and in compilations relevant to program administration, including claims processing and reimbursement. Such information is treated as confidential when it pertains to individual patients and is not

disclosed except as authorized by Department regulations on confidentiality and disclosure (see 45 CFR parts 5, 5b, and part 401 of this chapter).

[53 FR 6548, Mar. 1, 1988]

**§405.2134 Condition: Participation in network activities.**

Each facility must participate in network activities and pursue network goals.

[51 FR 30362, Aug. 26, 1986]

**§405.2135 Condition: Compliance with Federal, State and local laws and regulations.**

The ESRD facility is in compliance with applicable Federal, State and local laws, and regulations.

(a) *Standard: licensure.* Where State or applicable local law provides for the licensing of ESRD facilities, the facility is:

(1) Licensed pursuant to such law; or

(2) Approved by the agency of such State or locality responsible for such licensing as meeting the standards established for such licensing.

(b) *Standard: licensure or registration of personnel.* Each staff member is currently licensed or registered in accordance with applicable law.

(c) *Standard: conformity with other laws.* The facility is in conformity with applicable laws and regulations pertaining to fire safety, equipment, and other relevant health and safety requirements.

**§405.2136 Condition: Governing body and management.**

The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility. The governing body receives and acts upon recommendations from the network organization. The governing body appoints a chief executive officer